

Remarks

In the Office action dated March 26, 2008, a restriction requirement was made categorizing the claims into five separate inventions, Groups I-V. In the requirement, the Examiner stated that the Inventions of Groups I, II, III and V are related as process of making and product made. With respect to the invention of Group IV, the Examiner stated that “the invention of Group IV does not have sufficient antecedent in the claims from which they depend.” It is noted that the invention of Group IV, claims 20-26, depend from claim 16, the only claim categorized in the invention of Group II. Although the Applicant respectfully believes that the steps defined in method claims 20-26 further limit the method of claim 16, in order to expedite the prosecution of this case, claims 16 and 20-26 have been canceled.

In response to the above restriction requirement, the Applicant elected the invention of Group V, claims 27-30 defining the product made, for prosecution in a response to the restriction requirement dated April 22, 2008. The Examiner then rendered rejections of claims 27-30 in subsequent Office actions dated August 20, 2008 and September 4, 2009.

In light of the newly amended claims herein, the Applicant respectfully believes that the claims are now limited to two inventions: I. Claims 1 and 3-15 for the process of making the face-seal interface, and II. Claims 17-19 and 27-31 for the face-seal interface. These two inventions are clearly related as process of making and product made.

In accordance with the MPEP §821.04, the propriety of a restriction requirement should be reconsidered when all the claims directed to the elected invention are in

condition for allowance, and the nonelected invention(s) should be considered for rejoinder. Rejoinder involves withdrawal of a restriction requirement between an allowable elected invention and a nonelected invention and examination of the formerly nonelected invention on the merits.

In order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim. A withdrawn claim that does not require all the limitations of an allowable claim will not be rejoined. Furthermore, where restriction was required between a product and a process of making and/or using the product, and the product invention was elected and subsequently found allowable, all claims to a nonelected process invention must depend from or otherwise require all the limitations of an allowable claim for the claims directed to that process invention to be eligible for rejoinder. See MPEP § 821.04(b). In order to retain the right to rejoinder, applicant is advised that the claims to the nonelected invention(s) should be amended during prosecution to require the limitations of the elected invention. **Failure to do so may result in a loss of the right to rejoinder.**

For reasons discussed hereinafter, Applicant respectfully submits that the claims for the product, claims 17-19 and 27-31, as now amended are in condition for allowance, and that the claims for the method of making the product, claims 1 and 3-15, have been amended to require all the limitations of the allowable product claims. Thus, Applicant respectfully believes that he has preserved his right to have the process claims rejoined with the product claims and, should the Examiner find the product claims allowable, that the method claims be rejoined with the product claims.

In an Office action dated September 4, 2009, the Examiner rejected claims 27-30 under 35 U.S.C. 112, first paragraph, as being based on a non-enabling disclosure; and under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 was rejected under 35 U.S.C. 103(a) as being unpatentable over Matula et al. US 2006/0231103. Claims 27 and 29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chen US 2003/0122446. Claims 27, 29 and 30 were rejected under 35 U.S.C. 103(a) as unpatentable over Yates US 6,672,548 in view of Chen US 2003/0122446. Claim 28 was rejected under 35 U.S.C. 103(a) as being unpatentable over Yates US 6,672,548 in view of Chen US 2003/0122446 and further, in view of Barnett et al. US 2006/0076018.

Applicant respectfully traverses all of the above rejections for reasons discussed hereinafter.

With respect to the rejection of claims 27-30 under 35 U.S.C. 112, first and second paragraphs, Applicant respectfully submits that the particular type and size of particles used to fill the elastomeric bladder type of the face-seal interface would merely amount to selecting particles of a size and shape that could be filled into the bladder and flow once inside the bladder. An example of such particles is discussed in paragraphs 63 and 64 of this application with respect to the embodiment illustrated in figures 12 A-B. Bladder 270 is filled with loose fine powder 280 made of solid or hollow particles. Such disclosure alone is considered to enable one of ordinary skill in the art to know how to make and use the claimed invention without undue experimentation.

In accordance with the MPEP §2164.01(a), there are other factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. One factor is the state of the prior art. The Applicant offers the following list of prior art references as evidence that the selection of particles would not amount to “undue experimentation”. These references have been listed in an IDS form SB-08A for Examiner’s review.

<u>Prior Art References</u>	<u>Inventors</u>
US 4022200 A	Jonson; Bjorn
US 2877764 A	Galleher, Ellis A. Jr.
US 2749910 A	Faulconer, Albert Jr.
US 5592938 A	Scarberry; Eugene N. et al.
US 3052887 A	Socklel, William G. et al.
US 2917045 A	Schildknecht, Calvin E. et al.
US 6615832 B1	Chen; David E.
US 6631718 B1	Lovell; John R.
US 4665570 A	Davis; James E. P.

The Jonson patent discloses a medical facemask having sealing part (30) consisting of jacket (6) which is formed of a soft, elastic material, such as latex sheet, which air-tightly contacts the face of the patient. The interior of the sealing part (3) is filled with a powder material (7) such as small plastic material particles. With suction device (14), air is evacuated from the sealing part. As the sealing part is evacuated, it stiffens and maintains the sealing formation about the face of the patient.

The Galleher, Jr. patent discloses a facemask having a self contouring facial seal comprising peripheral cuff or cell (5) having wall (8) of extremely flexible, soft and

resilient material and which is filled with finely ground or divided foamed or sponge latex particles (P) (see column 2, lines 41-50). The particles are porous and resilient as distinguished from solid, hard particles such that they will compress under slight pressure (see column 3, lines 3-16). The particles are lubricated, for example, with soapstone (Georgia Talc 450 or 650/ magnesium silicate) to remove any hindrance to freedom of movement (see column 3, lines 17-21). The cuff (5) includes valve (10) which is opened as the facemask is lightly pressed against the face thereby forcing air out of the cuff. Once the cuff is sealed against the face and formed to the individual, the valve is closed and the facemask cuff maintains the imposed facial formation until the valve (10) is again opened (see column 3, lines 28-45).

The Faulconer, Jr. patent discloses a facemask with bladder (16) molded from rubber latex and filled with granular material (22) such as vinyl plastic granules or molding powder (see column 3, lines 5-13). The bladder (16) has vacuum hose (30) connected thereto for evacuating air from the bladder to provide a custom fit to the patient's face (see column 3, line 25 through column 4, line 7). The manner in which the facemask is conformed to the patient's face is disclosed in column 4, lines 8-34).

The Scarberry, et al. patent discloses a facemask as illustrated in figure 5 which has seal (86) comprised of a flexible rubber wall (92) filled with Styrofoam plastic beads. A vacuum connection (98) permits drawing a partial vacuum in space (94) (see column 6, lines 23+).

The Sockel, et al. patent discloses a facemask having seal member (1) comprising an endless flexible tube of flexible material such as vinyl plastic which has flexibility as well as elasticity (see column 2, lines 13-17). The tube (1) is partially filled with a fluid

(2). Air is expelled from the tube through a valve (not shown) as liquid is introduced through a second valve (not shown) (see column 2, lines 17-21). The fluid may be air or gas, liquid, semi-liquid, or solid having a high viscosity. A suitable liquid may be water or a mixture of water and glycerin, or it may be a syrup-like material, or may be a flowable or plastic solid such as grease or a “jell” [gel] (see column 3, lines 1-15).

The Schildknecht, et al. patent discloses a facemask with rim (12) defined by a relatively thin walled membrane (30) (see column 4, lines 3-8). The rim is filled with insoluble organic polymers in the form of discrete particles (see column 4, lines 34+). The composition filler material enables the facemask rim to be pressed to a desired contour for substantially exact conformity with the face of any patient. The rim retains such shape as long as desired. The filler material is stable and will not harden upon aging. The mask rim retains such pliability indefinitely (see column 6, lines 1-13).

The Chen patent discloses a facemask having interface pad (26) comprised of a bladder (28) that is filled with suitable gel material, such as silicone, urethane or the like (see column 4, lines 27-35). Other gel materials may be used such as hydrogels, PVC gel or polyurethane gel (see column 7, lines 28-32).

The Lovell patent discloses a nose mask with face seal (2) comprised of a bladder filled with silicone gel (see column 7, lines 45-58).

The Davis patent discloses a facemask with bladder seal (18) filled with oil, water, clay or powder (see column 4, lines 5-7).

Based on Applicant’s disclosure and in light of the above prior art references, Applicant respectfully submits that the specification does provides sufficient evidence that would enable one of ordinary skill in the art to make and use the invention without

“undue experimentation”, especially in light of the knowledge already in existence in this particular field of endeavor.

For all the reason advanced supra, Applicant respectfully requests that the rejections under 35 U.S.C. 112, first and second paragraphs, be reconsidered and withdrawn.

Without necessarily acquiescing with the prior art rejections rendered against the claims in the Office action dated September 4, 2009, in light of the prior art of record and the prior art listed above, Applicant has amended the claims to distinguish the subject invention over the prior art by claiming the specific structure of the outer surface of the face-seal interface.

Independent product claim 17 has been amended in accordance with the MPEP §2113 in “product-by-process” format to more clearly describe the face-seal interface for a respiratory mask configured and adapted to provide a seal between peripheral boundaries of said respiratory facemask and a patient’s face made by the method of claim 1 thereby having a micro-cratered outer surface covered with a dry powder acting as a lubricant. Claims 18, 19 and 27-30 have been amended to depend from claim 17. New claim 31 depended on claim 17 has been added.

Independent process claim 1 has been amended to more clearly describe the steps of the method of making the face-seal interface for a respiratory mask such that it is molded to be configured and adapted to provide a seal between peripheral boundaries of said respiratory facemask and a patient’s face and that by adding a predetermined amount of the at least one additive to the molten mixture of mineral oil and polymer proportionately in excess of an amount of additive that is soluble in the mixture at room

temperature, the particles in the mixture will precipitate and migrate after solidification of the elastomer to the outer surface of the interface thereby forming micro-craters on the outer surface and covering the outer surface with a dry powder thereby acting as a lubricant. Such a process is clearly supported throughout the specification, particularly in paragraphs 15-19, 40, 45, 47-49 and 55, and illustrated in figures 2-7.

Applicant respectfully submits that none of the prior art of record, alone or in combination, renders the now claimed face-seal interface made by the specific process resulting in the face-seal interface having a micro-cratered outer surface covered with dry powder unpatentable.

It is further noted that the claims herein have been amended in parallel fashion to the claims in Applicant's related Applications No. 11/242,815. The following references were cited during the prosecution of Application No. 11/242,815 and have also been listed on the IDS form SB-08A for the Examiner's consideration.

US 4,369,284	Chen
US 6,852,776	Ong et al.
US 7,053,145	Tasaka et al.
US 2005/0101693	Arbogast et al.
US 2006/0020061	Knoll et al.

It is noted that claim 1-18 in Application No. 11/242,815 were found to be patentable over the above cited references.

The following references were cited during the prosecution of Applicant's related application No. 11/222,288 and have also been listed on the IDS form SB-08A for the Examiner's consideration.

US 6,183,514	Becker
US 2002/0193878	Bowman
US 6,390,885	Brooks
US 5,630,844	Dogan et al.
US 2003/0195623	Marchitto et al.
US 5,370,688	Schultz et al.
US 6,117,176	Chen
US 2004/0073305	Schneider-Nieskens

Of the above references, the Dogan et al. reference is considered the most pertinent prior art reference of record that describes the texture of the outer surface of the prosthesis. **However, Applicant wishes to emphasize that the surface structure of the Dogan, et al. prosthesis is quite different from the surface structure of Applicant's invention.** In column 8, lines 51-54, the Dogan, et al. reference discloses, "Prior to or after vulcanization of the silicone layer, the outer silicone layer may be ablated with sodium chloride to form a textured surface on the outer silicone layer, as is shown in FIGS. 2 and 3". The **ablation** process of Dogan, et al. forms an outer surface quite different from the **precipitation** process of Applicant's invention. As illustrated in FIGS.2 and 3 of the Dogan, et al. reference the outer surface is ablated to form scratches, ruts and grooves, not micro-craters as illustrated in figures 2-7 of the instant application. Applicant's precipitation process involves the over-saturation of additive to the mixture, as claimed, which additives then precipitate to the surface during the formation of the elastomeric polymer during the cooling phase thereby creating the micro-craters on the surface thereof.

All amendments made herein find full support in this application as originally filed. Thus, no new matter has been introduced by the manner of amending this application.

Accordingly, all of the pending claims, i.e., claims 1, 3-15, 17-19 and 27-31, are believed to be in condition for allowance and issuance of a notice of allowance is respectfully requested.

The Examiner is requested to contact the undersigned if there are any questions regarding this communication.

Respectfully submitted,

/Henry J. Recla/

Henry J. Recla
Patent Agent
Reg. No. 60,103

IP-R-Us, LLC
13006 Emmet Ct.
Woodbridge, VA 22192
Tel.: (703) 216-9965
Fax: (703) 491-7189
PTO Customer No. 91368